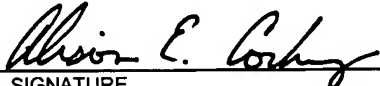


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U.S. Patent and Trademark Office, U.S. Department of Commerce
JUL 16 2005

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 112981.126US1
INTERNATIONAL APPLICATION NO. PCT/US2003/041392	INTERNATIONAL FILING DATE 22 December 2003	U.S. APPLICATION NO. (if known, see 20 CFR 1.5) TBA 10/538991
TITLE OF INVENTION HIGH PRESSURE COMPACTION FOR PHARMACEUTICAL FORMULATIONS		
APPLICANT(S) FOR DO/EO/US SMITH, Thomas J., GAUZER, Gene		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input checked="" type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> has been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <p>a. <input type="checkbox"/> is attached hereto.</p> <p>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).</p> <p>b. <input type="checkbox"/> have been communicated by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A preliminary amendment.</p> <p>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information: 1.) Petition to Correct Priority Under 37 CFR 1.182 2.) International Search Report for PCT/US2003/041392</p>		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Express Mail Label No. EV621476689US
Date of Deposit: June 15, 2005U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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U.S. APPLICATION NO. (if known, see 37 CFR 1.5) TBA 10/538991		INTERNATIONAL APPLICATION NO. PCT/US2003/041392		ATTORNEY'S DOCKET NUMBER 112981.126US1	
The following fees have been submitted				CALCULATIONS PTO USE ONLY	
21. <input checked="" type="checkbox"/> Basic national fee..... \$300				\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... \$100 All other situations..... \$200				\$ 200.00	
23. <input checked="" type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... \$100 International Search Report prepared and provided to the Office..... \$400 All other situations..... \$500				\$ 100.00	
TOTAL OF 21, 22 and 23 =				\$ 600.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
28 - 100 =	0 /50 =		x \$250	\$	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(h)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$ 50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
TOTAL OF ABOVE CALCULATIONS =				\$ 600.00	
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$ 300.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).				+	\$
TOTAL NATIONAL FEE =				\$ 300.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$
TOTAL FEES ENCLOSED =				\$ 300.00	
				Amount to be refunded:	\$
				Amount to be charged:	\$ 300.00
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>08-0219</u> in the amount of \$ <u>300.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08-0219</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p>					
<p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p>					
SEND ALL CORRESPONDENCE TO:					
Wilmer Cutler Pickering Hale and Dorr LLP 60 State Street Boston, MA 02109 (617) 526-6000 (617) 526-5000 (Facsimile)					
 SIGNATURE Alison E. Corkery NAME 52,770 REGISTRATION NUMBER					



10/538991
JC09 Rec'd PCT/PTO 15 JUN 2005

Commissioner for Patents
Washington, DC 20231
www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
60/435,448	12/20/2002		80	TJS-007			

CONFIRMATION NO. 2387

Lisa M. Portscher
15 Braeburn Road
Hyde Park, MA 02136

FILING RECEIPT



OC000000009576584

Date Mailed: 02/28/2003

Receipt is acknowledged of this provisional Patent Application. It will not be examined for patentability and will become abandoned not later than twelve months after its filing date. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. **If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).**

Applicant(s)

Thomas J. Smith, Weston, MA;

If Required, Foreign Filing License Granted: 02/27/2003

Projected Publication Date: None, application is not eligible for pre-grant publication

Non-Publication Request: No

Early Publication Request: No

**** SMALL ENTITY ****

Title

Large crystalline formulations for sustained release delivery of anti-Parkinson agents

LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING

LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

VERIFICATION OF MAILING BY EXPRESS MAIL

I, LISA M. PORTSCHER, state that I have mailed the documents identified on the attached Transmittal Form/Cover Sheet to the U.S. Patent and Trademark Office, addressed to the Commissioner for Patents, Washington, D.C. 20231, via Post Office to Addressee, Label No. EU 792050075, at the HYDE PARK, MA Post Office. I have made this verification after depositing the correspondence, but within one business day after depositing the correspondence.

EU 792050075 US

Lisa M. Portscher
(Signature)

Date of Signature: 12/20
Time of Signature: 11:30 AM
Date of Deposit: 12/20
Time of Deposit: 10:34 AM

Re: Application Number: Unknown

Filing Date: 12/20/02

Title: Large Crystalline Formulations for Sustained Release
Delivery of Anti-Parkinson Agents

First Named Inventor: Smith, Thomas J.

Attorney Docket Number: TJS - 007

Filed by: Lisa M. Portscher

10/538991

PTO/SB/16 (10-01)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No.

EU792050075

JC09 Rec'd PCT/PTO 15 JUN 2005

INVENTOR(S)					
Given Name (first and middle [if any])		Family Name or Surname		Residence (City and either State or Foreign Country)	
Thomas J.		Smith		Weston, MA	
<input type="checkbox"/> Additional inventors are being named on the _____ separately numbered sheets attached hereto					
TITLE OF THE INVENTION (500 characters max)					
Large Crystalline Formulations for Sustained Release Delivery of Anti-Parkinson Agents					
Direct all correspondence to: CORRESPONDENCE ADDRESS					
<input type="checkbox"/> Customer Number		<input type="text"/>			
OR		Type Customer Number here			
<input checked="" type="checkbox"/> Firm or Individual Name		Lisa M. Portscher			
		PATENT TRADEMARK OFFICE			
Address		15 Braeburn Road			
Address					
City		Hyde Park	State	MA	ZIP 02136
Country		USA	Telephone	617-361-5434	Fax
ENCLOSED APPLICATION PARTS (check all that apply)					
<input checked="" type="checkbox"/> Specification		Number of Pages		<input type="checkbox"/> CD(s), Number	
<input type="checkbox"/> Drawing(s)		Number of Sheets		<input type="checkbox"/> Other (specify)	
<input type="checkbox"/> Application Data Sheet. See 37 CFR 1.76					
METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT					
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.				FILING FEE AMOUNT (\$)	
<input checked="" type="checkbox"/> A check or money order is enclosed to cover the filing fees					
<input type="checkbox"/> The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number.		<input type="text"/>		\$80.00	
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.					
The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.					
<input checked="" type="checkbox"/> No.					
<input type="checkbox"/> Yes, the name of the U.S. Government agency and the Government contract number are: _____					

Respectfully submitted,

SIGNATURE



TYPED or PRINTED NAME Lisa M. Portscher

TELEPHONE 617-361-5434

Date

12/20/02

REGISTRATION NO.

(if appropriate)

Docket Number:

N/A

TJS-007

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

FEE TRANSMITTAL

for FY 2003

Patent fees are subject to annual revision.

☒ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 80.00

Complete if Known

Application Number	Unknown
Filing Date	12/20/2002
First Named Inventor	Smith, Thomas J.
Examiner Name	Unknown
Art Unit	Unknown
Attorney Docket No.	TJS-007

METHOD OF PAYMENT (check all that apply)

☒ Check ☐ Credit card ☐ Money Order ☐ Other ☐ None

☐ Deposit Account:

Deposit Account Number
Deposit Account Name

The Commissioner is authorized to: (check all that apply)

☐ Charge fee(s) indicated below ☐ Credit any overpayments

☐ Charge any additional fee(s) during the pendency of this application.

☐ Charge fee(s) indicated below, except for the filing fee to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description	Fee Paid
1001 740	2001 370	Utility filing fee	
1002 330	2002 165	Design filing fee	
1003 510	2003 255	Plant filing fee	
1004 740	2004 370	Reissue filing fee	
1005 160	2005 80	Provisional filing fee	80.00
SUBTOTAL (1)			(\$ 80.00)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

Total Claims	Extra Claims	Fee from below	Fee Paid
Independent Claims	-20** =	X	=
Multiple Dependent	-3** =	X	=
		0	0

Large Entity Fee Code (\$)	Small Entity Fee Code (\$)	Fee Description
1202 18	2202 9	Claims in excess of 20
1201 84	2201 42	Independent claims in excess of 3
1203 280	2203 140	Multiple dependent claim, if not paid
1204 84	2204 42	** Reissue independent claims over original patent
1205 18	2205 9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) (\$ 0.00

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Small Entity

Fee Code (\$)	Fee Code (\$)	Fee Description	Fee Paid
1051 130	2051 65	Surcharge - late filing fee or oath	
1052 50	2052 25	Surcharge - late provisional filing fee or cover sheet	
1053 130	1053 130	Non-English specification	
1812 2,520	1812 2,520	For filing a request for ex parte reexamination	
1804 920*	1804 920*	Requesting publication of SIR prior to Examiner action	
1805 1,840*	1805 1,840*	Requesting publication of SIR after Examiner action	
1251 110	2251 55	Extension for reply within first month	
1252 400	2252 200	Extension for reply within second month	
1253 920	2253 460	Extension for reply within third month	
1254 1,440	2254 720	Extension for reply within fourth month	
1255 1,960	2255 980	Extension for reply within fifth month	
1401 320	2401 160	Notice of Appeal	
1402 320	2402 160	Filing a brief in support of an appeal	
1403 280	2403 140	Request for oral hearing	
1451 1,510	1451 1,510	Petition to institute a public use proceeding	
1452 110	2452 55	Petition to revive - unavoidable	
1453 1,280	2453 640	Petition to revive - unintentional	
1501 1,280	2501 640	Utility issue fee (or reissue)	
1502 460	2502 230	Design issue fee	
1503 620	2503 310	Plant issue fee	
1460 130	1460 130	Petitions to the Commissioner	
1807 50	1807 50	Processing fee under 37 CFR 1.17(q)	
1806 180	1806 180	Submission of Information Disclosure Stmt	
8021 40	8021 40	Recording each patent assignment per property (times number of properties)	
1809 740	2809 370	Filing a submission after final rejection (37 CFR 1.129(a))	
1810 740	2810 370	For each additional invention to be examined (37 CFR 1.129(b))	
1801 740	2801 370	Request for Continued Examination (RCE)	
1802 900	1802 900	Request for expedited examination of a design application	

Other fee (specify)

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) (\$ 0.00

SUBMITTED BY

Name (Print/Type)	Lisa M. Portscher	Registration No. (Attorney/Agent)	N/A	Telephone	617-361-5434
Signature	Lisa M. Portscher	Date	12/20/02		

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

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10/538991

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PHONE (617) 761-2434	PHONE ()
ZIP + 4 02136	ZIP + 4 20004

FOR PICKUP OR TRACKING CALL 1-800-222-1811

www.usps.com

The following have been received by the U.S. Patent and Trademark Office on the date stamped hereon:
Patent Application Transmittal Form

- ☐ Non-Provisional ☒ Provisional ☐ Design ☐ CPA of \$ ☐ Reissue of \$
- ☐ Divisional, ☐ Continuation, or ☐ C-I-P of Prior App. #
- ☒ Fee Transmittal Form \$ 80.00
- ☒ Applicant claims small entity status
- ☒ Specification (Total Pages 16)
- ☐ Drawing(s) (Total Sheets)
- ☐ Formal ☐ Informal
- ☐ Oath or Declaration (Total Pages)
- ☐ Newly executed (☐ original ☐ copy)
- ☐ Copy from a prior application
- ☐ Deletion of Inventors
- ☐ Application Data Sheet
- ☐ CD-ROM or CD-R in duplicate, large table or Computer Program
- ☐ Assignment Papers (coversheet and documents)
- ☐ 37 CFR 3.73(b) Statement
- ☐ Power of Attorney
- ☐ English Translation Document
- ☐ Information Disclosure Statement, PTO-1448 and ____ copies of IDS Citations
- ☐ Preliminary Amendment
- ☐ Certified Copy of Priority Document
- ☐ Nonpublication Request under 35 U.S.C. 122(b)(2)(B)(i)
- ☐ Nucleotide and/or Amino Acid Sequence Submission
- ☐ Computer Readable Form (CRF)
- ☐ Specification Sequence Listing on:
☐ CD-ROM or CD-R (2 copies); or
☐ Paper
- ☐ Statements verifying identity of above copies

J1046 U.S. PTO

60/435448



12/20/02

Title: Large Crystalline Formulations for Sustained Release Delivery of Anti-Parkinson Agents

1st Inventor: Smith, Thomas J.

Filed by: Lisa M. Portcher

Date Mailed: 12/20/02

Express Mail Label No: EU792050075

Attorney Docket No:

TJS-007